From: "Paul Rodgers" <prodgers@usit.net>, on 1/18/98 12:44 PM:
To: George Mitchell@OD@FDACVM

Following are comments on Docket No. 97N-0217 by the American Sheep Industry Association. The text of the comments follow in this e-mail message and are attached in a Microsoft Word 6.0.1 file also. If these comments are not recieved in full please notify: prodgers@usit.net

Docket No. 97N-0217 --"Proposals to Increase the Availability of Approved Drugs for Minor Species and Minor Uses"

We are writing on behalf of the American Sheep Industry Association (ASI). ASI represents approximately 80,000 sheep producers in the United States through its 50 state member associations as well as product manufacturers and other allied industry groups.

ASI appreciates the opportunity to comment on this discussion draft and the agency's efforts to address options to increase the availability of approved drugs for minor animal species and minor uses. We are disappointed, however, that the agency did not publish in the discussion draft many regulatory options for comment. In fact, of the 11 major initiatives outlined in the draft, nine require legislative actions. It was our understanding, through discussions with the agency during deliberations on the Animal Drug Availability Act of 1996 (ADAA), that CVM had a regulatory framework visualized for making major improvements to the minor species/minor use drug availability problem and needed the 18 months called for in the bill to complete what was well underway. There have been two legislative vehicles, the ADAA and the FDA reform bill, through which legislative changes to affect minor species/minor use could have been approached should the agency have anticipated and proposed these changes earlier. Through the process of analyzing comments on this discussion draft we encourage CVM to give more serious consideration to regulatory options as was initially indicated.

Modification of Extra-label Provisions

We agree with CVM that extra-label use is not the entire solution to the minor species drug availability problem. We reference the comments by the American Feed Industry Association on the use of a Compliance Policy Guide (CPG) as a means for implementing the Veterinary Feed Directive (VFD) under current statutory authority and we agree with their comments. We also reference the comments of the Coalition for Animal Health on this issue and agree with their proposed solution: to amend the VFD provisions of the ADAA rather than amend the Animal Medicinal Drug Use Clarification Act (AMDUCA). We believe that VFD is a clearly defined, well structured process for distributing minor species drugs through feed and could be implemented under current statute using the CPG approach at least as an interim measure. ASI will support amending the ADAA, if necessary, to provide a permanent statutory solution.

Concerning the agency's question concerning reproductive hormones and implants; ASI believes that reproductive hormones and implants and other non-therapeutics should be included under extra-label provisions for minor species and minor uses.

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resources to make major contributions to the minor food and fiber species and uses. We feel that food and fiber uses should continue to be the priority.

Incentives to Pursue Minor Use Drug Approvals

ASI agrees with all of the proposed incentives listed under this section and we will support efforts to implement them. We believe that our industry would be better served to have more products available to treat our animals even if there is a risk that cast savings for generic competition is not realized for a longer period of time.

Data Sharing By Major Species NADA Holders

ASI believes that the proposals described in the discussion draft has merit provided the "takings" and liability issues can be reasonably resolved. We encourage CVM to develop this idea further and investigate mechanisms for ameliorating the above-mentioned potential problems.

Creation By Statute of a "Minor Use Animal Drug" Program

ASI supports the creation of a "Minor Use Animal Drug" category similar to the human orphan drug category with all the associated incentives. We supported this approach in the original deliberations on the ADAA. We are under the impression that a minor species/minor use work unit is, in fact, in existence currently. If this is not the case then we certainly support the development of one for the reasons outlined and structured in the manner described. A minor species/minor use work unit must certainly have adequate resources allocated to it in order for such a unit to have a functional impact.

Conditional Drug Approval for Minor Uses Involving Non-food Animals

ASI is on record supporting a conditional or streamlined approval process and we believe, as is the case with veterinary biologics, such processes could be an important method for moving product approvals into the market place. We believe that the proposals and limitations outlined in the discussion draft would be particularly useful. However, we believe CVM is in error in stating: "Food-producing animals should be excluded from this proposal" and to answer CVMs specific question: "Is the proposed process appropriately restricted to minor uses involving non-food animals?" Our answer is no; the proposed process should include food animals.

Alternate Approval Standard/Expert Review Panels for Minor Uses Involving Non-food Animals

ASI supports the proposals outlined under this section but again believes that CVM is in error in limiting them to non-food producing animals. To answer specific questions: We believe that animal caretakers will find drugs approved under the proposed alternate standard acceptable. The sheep industry does have the ability to assist CVM with expert review panels and would be willing to fund such panels as circumstances allows. As stated above, the proposed process should not be restricted to non-food animals.

International Harmonization

It is appropriately stated in the discussion draft that international harmonization: "could greatly increase the availability of approved drugs for minor uses in the United States", We strongly agree that: "if FDA could accept reviews for minor uses approved in other countries with equivalent regulatory systems, then obtaining approval in the U.S. would be potentially less costly and thus more attractive to sponsors". It is further stated in the discussion draft: "The agency could develop a system to assess the equivalency of approval systems in other countries and could then accept reviews from equivalent systems". ASI sees these statements as both true, positive and in the central spirit of enhanced global competitiveness and trade opportunities. There is precedent in assessing foreign equivalency in meat inspection regulations. The sheep industry is a good example of a species which is minor in the U.S. and which is major in other parts of the world. The opportunities afforded the sheep industry under international harmonization of review processes and data sharing are large. The competitiveness of the U.S. sheep industry can be vastly improved if products available to producers and veterinarians in countries like Australia and New Zealand are available here. We believe that there are sufficient numbers of foreign approvals to warrant the establishment of a CVM program to identify drugs approved in other countries and to work with potential sponsors on data needs. As stated in the discussion draft, no Congressional action is required in order to implement these processes and CVM but to add minor species/minor use to current harmonization activities. ASI urges CVM to proceed in implementing all aspects of the international harmonization for minor species/minor use drug approvals with all haste.

ASI appreciates the opportunity to comment on this docket, one which is very important to our industry. We also appreciate CVMs work and support of reforming the approval process for minor species /minor uses. If we can assist the agency in any way, please don't hesitate to contact us.

Submitted by:

Dr. Cindy Wolf
Chairman, ASI
Animal Health & Welfare Committee